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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,666	02/08/2002	Gyanendra Kumar	13172.0015U1	3290

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NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/072,666	KUMAR ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-138* is/are pending in the application.

4a) Of the above claim(s) *137 and 138* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on November 27, 2007 has been considered and acknowledged.

Status of the Application

2. Currently claims 1-138 are pending. Claims 137 and 138 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive for the reasons that follow.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-136 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6, 6,921,642 ('642) in view of Baner et al. (Nucleic Acids Res., Vol. 26 922), page 5073-5078, 1998).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the patent ('642) disclose and encompasses the instant method wherein the method in the patent comprises (a) bringing into contact one or more analyte samples and one or more reporter binding molecules (reporter primers), wherein each reporter binding molecule comprises a specific binding molecule and an amplification target circle, wherein each specific binding molecule interacts with an analyte directly or indirectly, incubating the analyte samples and the reporter binding molecules under conditions that promote interaction of the specific binding molecules and analytes; (c) bringing into contact the amplification target circles and one or more rolling circle replication primer(s), wherein the amplification target circles each comprise a single-stranded, circular DNA molecule comprising a primer complement portion, wherein the primer complement portion is complementary to at least one of the rolling circle primers and incubating the rolling circle replication primers and amplification target circles and the rolling circle replication primers; (d) incubating the rolling circle primers and amplification target circles under conditions that promote replication of the amplification target circles wherein replication of the amplification target circles results in the formation of presence of the corresponding analytes (see column 42, lines 32-39). However the method in the patent ('642) did not specifically disclose a decoupling

step to dissociate amplification target circle associated with analytes form specific binding molecule.

Baner et al. teach a method signal amplification of padlock probes by rolling circle replication, wherein Baner et al. teach that the method utilizes circularizing oligonucleotide probes or padlock probes in rolling circle amplification to enhance signal amplification (see page 5075, col. 1, paragraph 1 under results section), wherein Baner et al. disclose that the circularized probes can yield a powerful signal amplification and in order to proceed the reaction efficiently, the probes must be released from the link that forms with target molecules upon hybridization and ligation, and the replication of a circular probe that is hybridized to a target DNA strand (amplification target circle) with a nearby free end can efficiently participate in replication (see page 5073, col. 1, abstract, page 5078, col. 1, paragraph 2-3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting one or more analytes as taught by Kingsmore et al. with a step of decoupling amplification target circle as taught by Baner et al, to develop a sensitive method for the detection of multiple analyte(s) because Baner et al. explicitly taught the use of padlock probes in rolling circle amplification, and circularized probes can yield a powerful signal amplification and in order to proceed the reaction efficiently, the probes must be released from the link that forms with target molecules upon hybridization and ligation, and the replication of a circular probe that is hybridized to a target DNA strand (amplification target circle) with a nearby free end can efficiently participate in replication (see page 5073, col. 1, abstract, page 5078, col. 1, paragraph 2-3). Thus an ordinary skill in the art would have a reasonable expectation of success that the modification of the method taught by Kingsmore et al.

in a manner as taught by Baner et al. would result in an enhanced signal amplification for detecting one or more analytes and such modification of the method is considered as obvious over cited prior art.

Therefore the instant claims are rejected under obviousness-type of double patenting.

Response to arguments:

4. With regard to the rejection of claims 1-136 under 35 USC 103(a) as being obvious over Kingsmore et al. in view Baner et al., Applicants' arguments were fully considered and found unpersuasive for the reasons that follow. However, the rejection is withdrawn herein because Examiner notes that the claims in the patent ('642) and the instant invention are currently assigned to the same assignee and thus the claims are qualified to an obviousness type double patenting rejection, which is set forth as discussed above.

Applicants argue that Kingsmore et al. does not teach reporter binding molecule comprising the combination of specific binding molecule and an amplification target circle (ATC) and does not teach decoupling of amplification target circle from reporter binding primers. Applicants' further argue that Kingsmore et al. teach ATC associated with reporter binding primer via rolling circle replication primer prior to replication. The two arguments are contradictory to each other because while asserting that the reporter binding molecule lacks the combination of ATC and a specific binding molecule, also state that the reporter binding molecule is associated with ATC prior to and after replication, which indicate that the reporter binding molecule does comprise ATC and a specific binding molecule prior to replication as claimed.

Applicants' further assert that Baner et al. does not teach decoupling of ATC from associated specific binding molecules while arguing that Baner et al. disclose that to increase the efficiency of rolling circle replication of padlock probes, the topologic link formed between the padlock probe and its target sequence can be removed. As discussed above the contradictory statements do not deviate from the claimed decoupling of ATC.

Applicants' also argue that the instant claims require a specific compositions that interact together as well as a specific order and asserts that Kingsmore et al. teaches away from the instant claimed invention and argue that the Fig. 1, 11, 13, 14 of Kingsmore et al. requires that the ATC to not to be decoupled from the specific binding molecule and the office actions' reliance on Fig. 1 for such teaching is incorrect. Applicants' arguments are found unpersuasive. First, as discussed above Kingsmore et al. does teach the reporter binding molecule comprising ATC and a specific binding molecule. Second, the instant claims are in open 'comprising' format and do not recite that the steps need to be performed in a specific order. Thus as noted in MPEP 2111.03, any unrecited elements are within the scope of the instant method steps. Third, Kingsmore et al. disclose specifically in claim 1 of the patent that the steps are performed in any order by reciting prior to, simultaneously with or following' which clearly is within the scope of the instant claimed method and the method of Kingsmore et al. does broadly encompass that the steps performed in any order, which encompasses the instant claimed method, either a specified order or a non-specified order. With regard to the Applicants'arguments regarding teaches away, and that the rejection can not be sustained and even if such hypothetical dissociation ATC is applicable, Kingsmore et al.'s purpose in having a rolling circle replication as a part of reporter binding primer would be defeated and such modification of Kingsmore et al.'s method would

change the principle of operation of the method. Accordingly Kingsmore et al. teaches away from the instant claimed method and the combination of Baner et al. fails to make the instant claimed method obvious. Applicants' arguments are found unpersuasive. As noted in MPEP 2145, "A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994), a teaching away, is a significant factor to be considered as "teaching in". Thus the Figs 1, 11, 13 14 in combination with the claimed method of Kingsmore et al. is a significant 'teaching in' factor. Further, as noted in the 2144 (R-5) The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. >See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). There is no requirement that the prior art provide the same reason as the applicant to make the claimed invention. in the instant context, Kingsmore broadly disclose that the method steps can be performed in any order and thus the method is broader to modify in any direction, which is considered to be a significant 'teaching in' factor. Further, examiner notes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in thereferences themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d

1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, specific motivation is provided in the rejection, which states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting one or more analytes as taught by Kingsmore et al. with a step of decoupling amplification target circle as taught by Baner et al, to develop a sensitive method for the detection of multiple analyte(s) because Baner et al. explicitly taught the use of padlock probes in rolling circle amplification, and circularized probes can yield a powerful signal amplification and in order to proceed the reaction efficiently, the probes must be released from the link that forms with target molecules upon hybridization and ligation, and the replication of a circular probe that is hybridized to a target DNA strand (amplification target circle) with a nearby free end can efficiently participate in replication (see page 5073, col. 1, abstract, page 5078, col. 1, paragraph 2-3). Accordingly the arguments are found unpersuasive and are applicable to the obviousness rejection discussed above.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner,
Art Unit 1637

Prabha Chunduru 1/31/08
SURYAPRABHA CHUNDURU
PRIMARY EXAMINER